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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/428,122      | 10/27/1999  | ANDREW B. MURDIN     | 19721-007-(P        | 4261             |

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[REDACTED] EXAMINER

DEVI, SARVAMANGALA J N

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645

DATE MAILED: 10/09/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |                                      |                                      |
|---|--------------------------------------|--------------------------------------|
| <b>Office Action Summary</b>  | Application No.<br><b>09/428,122</b> | Applicant(s)<br><b>Murdin et al.</b> |
|   | Examiner<br><b>S. Devi, Ph.D.</b>    | Art Unit<br><b>1645</b>              |
| <b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>  |                                      |                                      |
| <b>Period for Reply</b><br>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>three</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.   |                                      |                                      |
| - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.<br>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.<br>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.<br>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).<br>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                      |                                      |
| <b>Status</b>   |                                      |                                      |
| 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jul 25, 2002</u>  |                                      |                                      |
| 2a) <input checked="" type="checkbox"/> This action is FINAL.      2b) <input type="checkbox"/> This action is non-final.   |                                      |                                      |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.   |                                      |                                      |
| <b>Disposition of Claims</b>  |                                      |                                      |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-16 and 18-44</u> is/are pending in the application.  |                                      |                                      |
| 4a) Of the above, claim(s) <u>5-9, 15, 20-24, and 27-37</u> is/are withdrawn from consideration.  |                                      |                                      |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed.  |                                      |                                      |
| 6) <input checked="" type="checkbox"/> Claim(s) <u>1-4, 10-14, 16, 18, 19, 25, 26 and 38-44</u> is/are rejected.  |                                      |                                      |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to.  |                                      |                                      |
| 8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.  |                                      |                                      |
| <b>Application Papers</b>   |                                      |                                      |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner.   |                                      |                                      |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.<br>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                                      |                                      |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.<br>If approved, corrected drawings are required in reply to this Office action.   |                                      |                                      |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.  |                                      |                                      |
| <b>Priority under 35 U.S.C. §§ 119 and 120</b>  |                                      |                                      |
| 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).<br>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:<br>1. <input type="checkbox"/> Certified copies of the priority documents have been received.<br>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.<br>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).<br>*See the attached detailed Office action for a list of the certified copies not received.   |                                      |                                      |
| 14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).<br>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.   |                                      |                                      |
| 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |                                      |                                      |
| <b>Attachment(s)</b>  |                                      |                                      |
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  |                                      |                                      |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  |                                      |                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____   |                                      |                                      |
| 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |                                      |                                      |
| 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)   |                                      |                                      |
| 6) <input type="checkbox"/> Other: _____  |                                      |                                      |

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## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

1) Acknowledgment is made of Applicants' amendment filed 08/14/02 (paper no. 16) in response to the Office Action mailed 02/25/02 (paper no. 15). With this, Applicants have amended the specification.

### **Status of Claims**

2) Claims 1-4, 10-14, 16, 18, 19, 25, 26, 38 and 39 have been amended via the amendment filed 07/25/02.

New claims 40-44 have been added via the amendment filed 07/25/02.

Claims 1-16 and 18-44 are pending.

Claims 1-4, 10-14, 16, 18, 19, 25, 26 and 38-44 are under examination.

### **Prior Citation of Title 35 Sections**

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

5) The objection to the specification made in paragraph 9(c) of the Office Action mailed 12/13/00 (paper no. 7) is withdrawn in light of Applicants' amendments to the specification.

### **Objection(s) Maintained**

6) The objection to the drawings made in paragraph 7 of the Office Action mailed 12/13/00 (paper no. 7) and maintained in paragraph 6 of the Office Action mailed 12/13/00 under 37 C.F.R 1.84 is withdrawn in light of Applicants' submission of formal drawings. These formal drawings have been approved by the Draftsperson.

### **Rejection(s) Withdrawn**

7) The provisional rejection of claims 1-4, 10-14, 16, 18, 19, 25 and 26 made in paragraph 10 of the Office Action mailed 12/13/00 (paper no. 7) under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 20, 21, 25-28, 32-35, 41 and 42 of co-pending application No. 09/376,770, is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).

8) The rejection of claims 1 and 25 made in paragraph 13 of the Office Action mailed 12/13/00 (paper no. 7) under 35 U.S.C § 102(b) as being anticipated by Longbottom (GenEmbl Database Accession number U72499, 25 September 1996) (Longbottom, 1996), is withdrawn in light of Applicants' amendments to the claims.

9) The rejection of claims 1, 4, 10-13, 16, 18, 19, 25 and 26 made in paragraph 14 of the Office Action mailed 12/13/00 (paper no. 7) under 35 U.S.C § 102(b) as being anticipated by Longbottom *et al.* (*Infect. Immun.* 66: 1317-1324, April 1998) (Longbottom *et al.*, 1998), is withdrawn in light of Applicants' amendments to the claims.

10) The rejection of claim 39 made in paragraph 21 of the Office Action mailed 02/25/02 (paper no. 15) under 35 § U.S.C. 112, first paragraph, as containing new matter, is withdrawn.

**Rejection(s) Maintained**

11) The rejection of claims 1-4, 10-14, 16, 18, 19, 25, 26, 38 and 39 made in paragraph 22 of the Office Action mailed 02/25/02 (paper no. 15) under 35 U.S.C § 112, first paragraph, as being non-enabled, is maintained for reasons set forth therein and herebelow. New claims 40-44 are now included under this rejection.

Applicants state that they have deleted the phrase "functional fragment thereof". Applicants assert that methods and computational programs for conducting sequence comparisons for homology are well known within the art and that the calculation of percent homology is well within the abilities of a skilled artisan. Applicants contend that a candidate polypeptide can be aligned with SEQ ID NO: 2 as described at line 14 on page 10 through line 2 of page 11. Applicants argue that since the calculation of percent identity does not require any algorithms, a skilled artisan can easily determine if a candidate "morphogen" has at least 75% of the amino acids identical with SEQ ID NO: 2. Applicants further state that claim 1 has been

amended to include the functional limitation that the polynucleotide induces an immune response, and that non-functional polypeptides do not fall within the scope of the claims.

Applicants' arguments have been carefully considered, but are non-persuasive. It is noted that claim 4 still includes the limitation "functional fragment thereof". It is not clear what do Applicants mean by the term "morphogen". Although one skilled in the art may be able to a polynucleotide that encodes a polypeptide having an amino acid sequence that is "at least 75%", "at least 80%" and "at least 90%" homologous to SEQ ID NO: 2, as set forth in paragraph 22 of the Office Action mailed 02/25/02 (paper no. 15), there is no guarantee that such a polynucleotide that is at least 25%, at least 20% or at least 10% dissimilar with the polynucleotide of SEQ ID NO: 1 would retain the immunogenic functions and would induce an immune response in a mammal against a strain of *Chlamydia*. Absent a concrete showing, it is not predictable that such a polynucleotide that is at least 25%, at least 20% or at least 10% dissimilar with the polynucleotide of SEQ ID NO: 1 would even remain *Chlamydia*-specific. The instant specification lacks a structure-function correlation for the instantly claimed polynucleotides that are at least 25%, at least 20% or at least 10% dissimilar with the polynucleotide of SEQ ID NO: 1. The rejection stands.

**Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

12) Claims 1-4, 10-14, 16, 18, 25, 26 and 38-44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is redundant in the recitation "polynucleotide comprising a polynucleotide" (see line 1).

(b) Claims 40 and 41 are vague and indefinite in the recitation "polypeptide having a sequence" (see line 2) without reciting that the sequence is an amino acid sequence. To obviate the rejection, it is suggested that Applicants replace the recitation with the recitation -- polypeptide having an amino acid sequence--.

(c) Claims 2-4, 10-14, 16, 18, 25, 26 and 38-44, which depend directly or indirectly, from one of the above-identified base claim(s), are also rejected as being indefinite, because of the vagueness or indefiniteness identified above in the base claim(s).

**Rejection(s) under 35 U.S.C. § 112, First Paragraph**

13) Claims 40-44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See paragraph 22 of the Office Action mailed 02/25/02 (paper no. 15) and paragraph 11 above for a detailed explanation.

**Objection(s)**

14) Claims 1, 40 and 41 are objected to for the following reasons:

(a) In line 9 of claim 1, for clarity, it is suggested that Applicants replace the recitation "by said mammal" with --in said mammal--.

(b) In line 5 of claim 1, for clarity, it is suggested that Applicants replace the recitation "to SEQ ID NO: 2" with --the amino acid sequence of SEQ ID NO: 2--.

(c) In line 4 of claim 1, for clarity, it is suggested that Applicants replace the recitation "polypeptide having a sequence" with --polypeptide having an amino acid sequence--.

(d) In line 2 of claims 40 and 41, for clarity, it is suggested that Applicants replace the recitation "homologous to SEQ ID NO: 2" with --homologous to the amino acid sequence of SEQ ID NO: 2--.

**Remarks**

15) Claims 1-4, 10-14, 16, 18, 19, 25 and 38-44 stand rejected.

16) The Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

18) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October, 2002

*SD*  
S. DEVI, PH.D.  
PRIMARY EXAMINER